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MINISTRY OF AGRICULTURE, FISHERIES AND FOOD

**FOOD STANDARDS COMMITTEE
REPORT ON
COLOURING MATTERS**



LONDON
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Food Standards Committee

The terms of reference of the Food Standards Committee are :

To advise the Secretary of State for Scotland, the Minister of Agriculture, Fisheries and Food, the Minister of Health, and as respects Northern Ireland the Secretary of State for the Home Department, on the composition, description, labelling and advertising of food with particular reference to the exercise of the powers conferred on Ministers by Sections 4, 5 and 7 of the Food and Drugs Act, 1955, and the corresponding provisions in enactments relating to Scotland and Northern Ireland.

The members of the Food Standards Committee are :

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Food Additives and Contaminants Sub-Committee

The terms of reference of the Food Additives and Contaminants Sub-Committee are :

To consider problems referred to the Sub-Committee by the Food Standards Committee in relation to all substances added to food, whether deliberately or not.

The members of the Food Additives and Contaminants Sub-Committee are :

Professor R. A. MORTON, F.R.S., Ph.D., D.Sc., F.R.I.C. (*Chairman*).
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Pharmacology Panel

The terms of reference of the Pharmacology Panel of the Food Additives and Contaminants Sub-Committee are :

To advise the Food Additives and Contaminants Sub-Committee on the toxicological aspects of food additives and contaminants.

The members of the Pharmacology Panel during the preparation of the report were :

Professor A. KEKWICK, M.A., M.B., B.Ch., F.R.C.P. (*Chairman*).
Department of Medicine, Middlesex Hospital.

Professor E. BOYLAND, D.Sc., Chester Beatty Research Institute.

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E. I. JOHNSON, Esq., M.Sc., F.R.I.C., Laboratory of the Government Chemist.

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Secretary :

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Standing Panel on Carcinogenic Hazards in Food Additives and Food Contaminants

The terms of reference of the Standing Panel on Carcinogenic Hazards in Food Additives and Food Contaminants are :

(1) To keep under review in the light of the report of the Panel on Carcinogenic Risks in Food Additives and Pesticides, the principles which should govern the assessment of carcinogenic hazards from substances.

(a) used or proposed to be used as food additives or

(b) liable to contaminate food through their use in agriculture in the storage, preparation or packaging of food.

(2) To advise in the light of these principles and on the basis of available evidence whether any individual substance constitutes a carcinogenic hazard to man.

(3) To indicate according to experience the lines along which new research in the subject might be pursued.

The members of the Standing Panel on Carcinogenic Hazards in Food Additives and Food Contaminants are :

Professor A. HADDOW, F.R.S., Ph.D., M.D. (*Chairman*), Chester Beatty Research Institute.

J. M. BARNES, Esq., C.B.E., M.B., M.R.C.S., L.R.C.P., Medical Research Council, Toxicology Research Unit, M.R.C. Laboratories.

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Professor J. W. ORR, M.D., F.R.C.P., Department of Pathology, The Medical School, University of Birmingham.

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Professor GEO. PAYLING WRIGHT, B.A., M.B., Ch.B., M.D., F.R.C.P., Guys Hospital Medical School (latterly Department of Physiology, Royal College of Surgeons).

Secretary :

R. GOULDING, Esq., M.D., B.Sc., Ministry of Health.

FOOD STANDARDS COMMITTEE

Report on the Review of the Colouring Matter in Food Regulations, 1957

The Food Standards Committee have considered and adopted a Report by their Food Additives and Contaminants Sub-Committee on the review of the Colouring Matter in Food Regulations. The Food Standards Committee fully endorsed the recommendation of their Sub-Committee that those colours for which there was incomplete toxicological evidence should be tested during the next five years if they were to be considered for retention on the United Kingdom list of permitted colouring matters. Manufacturers and users of these colours should establish their own priorities for the testing of colours to which they attach most importance. The Committee also considered that specifications for identity and purity for all colouring matters in the permitted list for use in food should be prepared as soon as possible.

The Report of the Food Additives and Contaminants Sub-Committee is as follows :

Introduction

1. In February 1961, the Government in a joint Press Notice issued by the Ministry of Agriculture, Fisheries and Food, the Ministry of Health, the Department of Health for Scotland and the Home Office, announced that a review was to be held of the colours permitted for use in food in the Colouring Matter in Food Regulations 1957, and invited representations from interested parties. At the request of the Food Standards Committee we, the Food Additives and Contaminants Sub-Committee, have now carried out this review of the Regulations and of the representations received from the organisations listed in Appendix I.

Scope of Review

2. Initially we reviewed the data currently available for all the so-called "coal-tar" colours listed in the First Schedule to the Colouring Matter in Food Regulations, 1957 and five other colours in favour of which representations were received. While our review was in progress, however, the negotiations concerning the possible entry of the United Kingdom into the European Economic Community took place, and we were asked to consider the nine coal-tar colours included in the directive for harmonisation issued by the Council of Ministers of the European Economic Community on colouring matters but not permitted for use in this country. In all, therefore, we have examined the following forty four coal-tar colours as well as the other colouring matters listed in Part II of the First Schedule of Colouring Matter in Food Regulations, 1957 :

(a) The 30 colours on the present United Kingdom permitted list ;

Ponceau MX
Ponceau 4R
Carmoisine
Amaranth
Red 10B
Erythrosine BS
Red 2G
Red 6B
Red FB

Ponceau SX
 Ponceau 3R
 Fast Red E
 Orange G
 Orange RN
 Oil Yellow GG
 Tartrazine
 Naphthol Yellow S
 Yellow 2G
 Yellow RFS
 Yellow RY
 Sunset Yellow FCF
 Oil Yellow XP
 Green S
 Blue VRS
 Indigo Carmine
 Violet BNP
 Brown FK
 Chocolate Brown FB
 Chocolate Brown HT
 Black PN

- (b) The 9 colours included in the European Economic Community List but not permitted in the U.K., which are

Chrysoine Yellow
 Quinoline Yellow
 Solid Yellow (Fast Yellow)
 Orange GGN
 Scarlet GN
 Ponceau 6R
 Indanthrene Blue RS
 Patent Blue V
 Black 7984

- (c) The 5 colours proposed in the representations :

Brilliant Blue FCF
 Rhodamine 6G
 Rhodamine B
 Violet 5BN
 Violet 6B

General Observations on Coal-Tar Colours

3. The Colouring Matter in Food Regulations 1957 largely implemented the recommendations made by the Food Standards Committee in their Report and Supplementary Report published in 1954 and 1955. These reports reviewed the toxicological evidence relating to these dyestuffs which were used as food colours. At that time a large number of synthetic colours was submitted by interested parties for examination and each colour was classified as A, B or C by the Committee.

4. The classification was as follows :

Class A—Colours which appeared to be innocuous when consumed in the amounts customarily used for colouring foods ;

Class B—Colours for which the evidence was scanty or conflicting but which there was no reason to suggest were potentially harmful in the amounts ordinarily consumed in foods :

Class C—Colours which had been shown to have, or were suspected to have, harmful effects on health.

5. The Food Standards Committee expressed concern in their reports in 1954 and 1955 about the lack of metabolic studies in this field and drew attention to the need for more research work in the toxicology of colours. Since the publication of the reports there appears to have been little or no investigational work carried out in support of the colours for which representations have been received. It is with regret that we have to record that the scientific literature reveals that for only comparatively few colours is there information as to chronic toxicity or carcinogenicity. In the case of almost all the colours there is still a lack of sufficiently comprehensive biological evidence to enable a conclusive opinion to be formed. Some work is proceeding on the pharmacological examination of colouring matters but to the best of our knowledge few details have as yet been published. It is our opinion that research is necessary on such problems as the products of metabolic breakdown, sites of storage, rate of elimination and the effects of the presence and positioning in the molecule of substituent groups and that such information together with long term studies in animals, rats and mice, is essential before the adequate control of the use of food colours can be achieved.

6. We asked our Pharmacology Panel to consider the toxicity data available for each colour. The Panel studied the data and assessed whether they provided sufficient details of the composition, purity and commercial usage of the colour, adequate information on the toxicological effect of the colour on animals and any evidence of effects on man. For an opinion on carcinogenicity the Pharmacology Panel sought the advice of the Standing Panel on Carcinogenic Hazards in Food Additives and Food Contaminants established by the Ministry of Health in 1960. The Pharmacology Panel classified the coal-tar colours into groups as set out in their Report (Appendix II). The references to the scientific work on which the Panels have based their classification are listed in Appendix III. The present position regarding these colours in certain other countries and the recommendations of international organisations have also been indicated in Appendix II. Having taken the advice of the Pharmacology Panel, we have concluded that the following colours should be withdrawn from the permitted lists :

Ponceau 3R

Ponceau SX

Naphthol Yellow S

Blue VRS

7. From information which we have received from chemical manufacturers we have concluded that Yellow RFS and Yellow RY should also be withdrawn from the list of permitted colours. It was represented to us that Yellow RFS was no longer suitable for retention on the permitted list because it contains several subsidiary dyes which on hydrolysis under mild conditions produce aminoazobenzene and aniline. In the case of Yellow RY we were informed that this colour differs in constitution from the designation given in the First Schedule to the Colouring Matter in Food Regulations 1957. We have recently learned that a new structural formula has been established which is as follows :—

2:6 -di-(4-sulphophenylazo)-1:3 -dihydroxybenzene-4-sulphuric acid.

8. In the absence of adequate evidence of testing we cannot give an unconditional clearance to more than a very few of the remainder of the

colours at present permitted but we consider that, on the available evidence, there is no need to prohibit their use in the amounts ordinarily used in food. We thus take a similar view to that taken by the Food Standards Committee in their previous reports, but we emphasise the importance of evidence of tests being provided, and we recommend that each of these colours (whether synthetic or natural) should be again reviewed not later than five years from now, and that any colour on which satisfactory evidence has not by then been received should be withdrawn on that ground from the permitted list. Should unfavourable evidence come to light earlier, we should expect the colour in question to be withdrawn from use immediately. The only coal-tar colours on the present permitted list for which there is reasonable evidence that the criteria of the Pharmacology Panel have been satisfied are Amaranth and Green S.

European Economic Community

9. Of the 9 coal-tar colours included in the European Economic Community list of permitted colours but not permitted in the United Kingdom we feel that only Black 7984 should be considered for addition in the United Kingdom revised list of permitted colours. The Panels have given the same classification to Black PN at present permitted in the United Kingdom and to Black 7984 in Appendix II. We therefore recommend in the interests of trade and international harmonisation of permitted colours that Black PN and Black 7984 should be provisionally permitted in any revised regulations subject to the recommendations in paragraph 8 that more complete toxicological evidence on these colours should be submitted within five years.

Consideration of Representations

10. Of the 5 coal-tar colours which we were asked to consider for addition to the permitted list the available evidence suggests that 4 are probably too toxic to be allowed in food. These are:—

Rhodamine B

Violet 6B

Brilliant Blue FCF

Rhodamine 6G

On the other, Violet 5 BN, we have received no evidence on which we can express an opinion. We therefore recommend that none of these colours should be added to the permitted list.

Blue Coal-tar Colours

11. In making our recommendations on the coal-tar colours we have appreciated that the proposed list of permitted coal-tar colours would not contain any blue colour which would be technically satisfactory for certain requirements of the trade. The evidence available on Brilliant Blue FCF and Blue VRS suggests probable toxicity and as we have already recommended earlier in the report these colours ought not to be allowed in food. In view of this we are prepared to give immediate consideration to any toxicological evidence which becomes available on any blue colour. We understand that toxicological studies have been carried out abroad on Patent Blue V but that this work has not yet been published.

British Industrial Biological Research Association

12. In paragraph 5 of our report we state that some work is proceeding on the pharmacological examination of colouring matters. In this connection we were pleased to learn that the British Industrial Biological

Research Association have started practical work on a number of coal-tar colours. We understand that this work has at present to be confined to short term tests and is being carried out to determine which colours should be submitted to full two-year trials when the Association's new laboratories are completed. We look forward to the time when the results of these studies will be available for our consideration.

Other Colours

13. We have considered the colours at present permitted in Part II of the First Schedule of the Colouring Matter in Food Regulations 1957 and recommend one change only in respect of those colours namely that titanium dioxide should be restricted to the surface colouring of food, as in the European Economic Community. In our study of the European Economic Community Council of Ministers' Directive on Colouring Matter in Foodstuffs 1962 we have also considered whether the United Kingdom regulations should permit the use of the copper derivatives of chlorophyll. The Directive of the European Economic Community permits the use of copper complexes of chlorophyll and chlorophyllins as colouring matters in foodstuffs. We asked the Pharmacology Panel to express a view on the possible use of the chlorophyll-copper and chlorophyllin-copper complexes and were advised that although the toxicological information suggests that the use of these complexes is unlikely to present a hazard to health, before their use in foodstuffs could be contemplated an assurance would be required that the complexes can be properly standardised, especially as regards "free" copper content; information would be required about their possible effect on the Vitamin C content of food; consideration would need to be given to analytical and consequent enforcement problems caused by the increase in the total copper content of foods to which they were added; and long-term studies would be required on a second species of animal. Taking account of this advice, but having regard also to the findings of the Food Standards Committee on copper derivatives of chlorophyll in their Supplementary Report on Colouring Matters 1955, we recommend that the copper complexes of chlorophyll and chlorophyllins should not be included in a list of permitted colours for use in foodstuffs.

14. We also asked the Pharmacology Panel to express an opinion on the suitability, for use as food colours, of three synthetically produced carotenoids, β -apo-8'-carotenal, β -apo-8'-carotenoic acid (C30) ethylester, and canthaxanthin. The Pharmacology Panel reported that β -apo-8'-carotenal and canthaxanthin had been tested in rats but that information was required about the results of long-term studies in another species. The Panel however felt that from the toxicological point of view there would be no objection to their use in food pending such studies, provided further consideration were given to the possible effects of an increased level of intake of Vitamin A arising from the use of these carotenoids as food colours. The information presented on β -apo-8'-carotenoic acid (C30) ethylester did not include any on long-term studies and was therefore inadequate for the Panel to express an opinion as to its suitability for use in food. After consideration of the Pharmacology Panel's views we see no objection to the use in food of β -apo-8'-carotenal and canthaxanthin, but as the information on β -apo-8'-carotenoic acid (C30) ethylester is inadequate to express an opinion we therefore do not recommend its use as a food colour.

15. We considered whether to alter the current position under which there was no limitation on the amount of colouring matter which could be added to any particular food (except that no colouring matter other than for marking could be added to fresh food—regulation 6 of the Colouring

Matter in Food Regulations, 1957). It was decided to recommend that there should continue to be no limitation on the quantity of colouring matter which could legally be added to food, since with good commercial practice the use of colouring matters in food should be self-limiting. We do however consider that regulation 6 should be amended to prohibit the colouring of citrus fruits.

Specifications

16. Considerable progress has been made in recent years in the drawing up of specifications for identity and purity of food additives. We therefore recommend that any revised regulations should prescribe specifications of purity for permitted food colours and that generally speaking the specifications for identity and purity for food colours published in 1963 by the World Health Organisation and the Food and Agriculture Organisation of the United Nations should be adopted because of the desirability of internationally accepted specifications of purity. Where no internationally agreed specifications are available regard should be had to the appropriate colour specification published by the British Standards Institution.

Summary of Conclusions and Recommendations

17. (a) Ponceau 3R, Ponceau SX, Naphthol Yellow S, Blue VRS, Yellow RFS, and Yellow RY should be withdrawn from the list of permitted coal-tar colours (paras. 6 and 7).
- (b) Black 7984 should be provisionally added to the list of permitted coal-tar colours (para. 9).
- (c) Titanium Dioxide should be permitted only for the surface colouring of food (para. 14).
- (d) β -apo-8'-carotenal and canthaxanthin should be permitted for colouring food (para. 14).
- (e) The colouring of citrus fruit should be prohibited (para. 15).
- (f) Specifications of purity of permitted colours should be prescribed (para. 16).
- (g) Any revised regulations made as a result of this report should be reviewed five years from now (para. 8).

March 1964

FSC/FAC/REP.4

APPENDIX I

Information and representations have been received from the following organisations and other interests concerned with the use of colouring matter in food.

Association of British Chemical Manufacturers.
British Baking Industries Research Association.
British Industrial Biological Research Association.
Cocoa, Chocolate and Confectionery Alliance.
County Councils Association.
Danish Embassy.
Derbyshire County Council.
Food Manufacturers' Federation Incorporated.
Fruit and Vegetable Canning and Quick Freezing Research Association.
Metropolitan Boroughs Standing Joint Committee.
Parliamentary Committee Co-operative Union Ltd.
L. J. Pointing and Son Ltd.
Roche Products Limited.
United States Department of Agriculture.

Report of the Pharmacology Panel of the Food Additives and Contaminants Sub-Committee (including the advice of the Standing Panel on Carcinogenic Hazards in Food Additives and Food Contaminants)

Review of the Colouring Matter in Food Regulations, 1957

Introduction

1. We were asked by the Food Additives and Contaminants Sub-Committee to study the information available for and to report on

- (a) the 30 so-called "Coal-Tar Colours" listed in the First Schedule to the Colouring Matter in Food Regulations, 1957.
- (b) 9 colours on the European Economic Community list that are not already listed in the Colouring Matter in Food Regulations, 1957.
- (c) 5 additional colours for which requests were received for inclusion in the United Kingdom list.

General Observations

2. We were supplied for each of the 44 coal-tar colours with individual data sheets purporting to contain all relevant published and unpublished information listed in Appendix III. We were conscious that additional unpublished information probably exists on some colours, particularly those proposed for the European Economic Community list and those permitted in the United States. But in the absence of such information we could only base our assessments on the information in the data sheets.

- 3. We studied the data sheet for each colour, assessing whether it provided
 - (i) sufficient details of the composition, purity and commercial usage of the colour;
 - (ii) adequate information on the toxicological effect of the colour on animals;
 - (iii) information on carcinogenicity;
 - (iv) any evidence of effects on man.

In no instance did the available evidence completely satisfy these four criteria nor had any colour been properly tested in accordance with the Ministry of Health's "Guide to Screening Tests for Carcinogenicity"⁽¹⁾.

4. We have made the following classification of the colours into tables on the basis of the scientific evidence listed in Appendix III. Each table shows the position of a colour in the United States of America, the European Economic Community, the Council of Europe (Partial Agreement) list of approved colours and in the United Kingdom under the Colouring Matter in Food Regulations 1957. Colours which are permitted in these countries have been indicated by a tick.

⁽¹⁾ Monthly Bulletin of the Ministry of Health and the Public Health Laboratory Service, 19, 108 (1960).

GROUP A

Colours that the available Evidence suggests are acceptable for use in Food

Colour	C.I. (1956) Number	United Kingdom 1957 Regulations	United States of America	European Economic Community	Council of Europe (Partial Agreement)
Amaranth	16185	✓	✓	✓	✓
Green S	44090	✓	—	✓ (provisional)	—

GROUP B

Colours that on the available Evidence may be regarded as provisionally acceptable for use in Food meantime, but about which further Information is necessary and which must be reviewed

Colour	C.I. (1956) Number	United Kingdom 1957 Regulations	United States of America	European Economic Community	Council of Europe (Partial Agreement)
Carmoisine	14720	✓	—	✓	✓
Erythrosine BS	45430	✓	✓	✓ (provisional)	✓
Fast Red E	16045	✓	—	—	✓
Ponceau 4R	16255	✓	—	✓	✓
Ponceau MX	16150	✓	—	—	—
Sunset Yellow FCF	15985	✓	✓	✓	✓
Tartrazine	19140	✓	✓	✓	✓
Indigo-Carmine	73015	✓	✓	✓	✓
Black PN	28440	✓	—	✓	✓
Black 7984	—	—	—	✓	—

GROUP C

Colours for which the available Evidence suggests possible Toxicity and which ought not to be allowed in Food without Evidence establishing their acceptability

Colour	C.I. (1956) Number	United Kingdom 1957 Regulations	United States of America	European Economic Community	Council of Europe (Partial Agreement)
Ponceau SX	14700	✓	✓	—	—
Ponceau 6R	16290	—	—	✓	✓
Scarlet GN	14815	—	—	✓	✓
Chrysoine S	14270	—	—	✓	✓
Orange GGN	15980	—	—	✓	—
Fast Yellow	13015	—	—	✓	✓
Indanthrene Blue	69800	—	—	✓	✓

GROUP D

Colours for which the available Evidence suggests probable Toxicity and which ought not to be allowed in Food

Colour	C.I. (1956) Number	United Kingdom 1957 Regulations	United States of America	European Economic Community	Council of Europe (Partial Agreement)
Ponceau 3R ...	16155	✓	—	—	—
Rhodamine B ...	45170	—	—	—	—
Rhodamine 6G ...	45160	—	—	—	—
Naphthol Yellow S ...	10316	✓	—	—	—
Blue VRS ...	42045	✓	—	—	—
BRELIANT BLUE FCF ...	42090	—	✓	—	—
VIOLET 6B ...	42640	—	✓	—	—

GROUP E

Colours for which the available Evidence was inadequate to enable an Opinion to be Expressed as to their suitability for use in Food

Colour	C.I. (1956) Number	United Kingdom 1957 Regulations	United States of America	European Economic Community	Council of Europe (Partial Agreement)
Red 6B ...	18055	✓	—	—	—
Red 10B ...	17200	✓	—	—	—
Red 2G ...	18050	✓	—	—	—
Orange G ...	16230	✓	—	—	—
OrangeRN ...	15970	✓	—	—	—
Oil Yellow GG ...	11920	✓	—	—	—
Oil Yellow XP ...	12740	✓	—	—	—
Quinoline Yellow ...	47005	—	—	✓	✓
Yellow 2G ...	18965	✓	—	—	—
Violet BNP ...	—	✓	—	—	—
Brown FK ...	included but no number	✓	—	—	—
Chocolate Brown FB	included but no number	✓	—	—	—

GROUP F

Colours for which no Information on Toxicity was available

Colour	C.I. (1956) Number	United Kingdom 1957 Regulations	United States of America	European Economic Community	Council of Europe (Partial Agreement)
Red FB ...	14780	✓	—	—	—
Yellow RFS ...	13011	✓	—	—	—
Yellow RY ...	14330	✓	—	—	—
Patent Blue V ...	42051	—	—	✓	✓
Violet 5BN ...	42650	—	—	—	—
Chocolate Brown HT	20285	✓	—	—	—

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Amaranth

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- ³ Willheim and Ivy.
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- ⁴ Nelson and Hagan.
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- ⁵ German Research Council, Dyestuff Commission.
Sixth Communication, 40 (1957).
- ⁶ Mannell, Grice, Lu and Allmark.
Journal of Pharmacy and Pharmacology, 10, 625 (1958).
- ⁷ Ryan and Wright.
Journal of Pharmacy and Pharmacology, 13, 492 (1961).
- ⁸ Hansen.
U.S. Department of Health, Education and Welfare, Bureau By-Lines, 3, 23 (1962).
[Submitted by British Industrial Biological Research Association.]

Green S

- ⁹ Goldblatt and Frodsham.
Unpublished information, submitted by I.C.I. Ltd. (1953).
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Unpublished information, submitted by I.C.I. Ltd. (1959).
- ¹¹ Walpole.
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Carmoisine

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Erythrosine BS

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- ¹⁹ Umeda.
Gann, 47, 51 (1956).
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- ²¹ Daniel.
Toxicology and Applied Pharmacology, 4, 572 (1962).
- ²² Hansen.
U.S. Department of Health, Education and Welfare, Bureau By-Lines, 3, 23 (1962).
[Submitted by British Industrial Biological Research Association.]

Fast Red E

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Green S

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Fast Red E

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Ponceau 4R

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Ponceau MX

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Sunset Yellow FCF

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Tartrazine

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Black PN

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Scarlet GN

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Indanthrene Blue

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Ponceau 3R

Rhodamine B

Rhodamine 6G

Naphthol Yellow S

Blue VRS

Brilliant Blue FCF

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Violet 6B

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Ponceau 6R

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Red 6B

Red 10B

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Red 2G

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Orange G

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Orange RN

Chrysoine S

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Oil Yellow GG

Oil Yellow XP

Quinoline Yellow

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Yellow 2G

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Violet BNP

Brown FK

Chocolate Brown FB

Red FB

Yellow RFS

Yellow RY

Patent Blue

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Violet 5BN

Chocolate Brown HT

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